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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/543,122	04/20/2006	Sudha Shenoy	67437-5020-US	2631

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EXAMINER	
HOWARD, ZACHARY C	
ART UNIT	**PAPER NUMBER**
1646	

MAIL DATE	DELIVERY MODE
12/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/543,122	SHENOY ET AL.	
	Examiner	Art Unit	
	Zachary C. Howard	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-35* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

Claims 1-35 are pending in consideration in the instant application.

Note

The sequence listing indicates that SEQ ID NO: 1, 3 and 5 are nucleic acid sequences, and that SEQ ID NO: 2, 4 and 6 are the corresponding encoded amino acid sequences. However, claim 7 of the instant application states that SEQ ID NO: 1-3 are amino acid sequences, and claim 9 states that SEQ ID NO: 4-6 are nucleic acid sequences. Applicants are requested to correct this inconsistency prior to examination.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-7 and 18-22, drawn to a modified arrestin comprising an arrestin and an ubiquitin moiety.

Group II, claims 8-17, 23 and 24, drawn to a nucleic acid encoding a modified arrestin, expression vectors and host cells comprising said nucleic acid, and substrates with a plurality of said cells.

Group III, claims 25-31, drawn to a method of screening compounds comprising exposing a cell expressing a modified arrestin to a test compound.

Group IV, claim 32, drawn to a modulator compound.

Group V, claim 33, drawn to a method of treating a subject comprising administering a modulator compound.

Group VI, claims 34 and 35, drawn to a method of treating a subject comprising administering a nucleic acid encoding a modified arrestin (gene therapy).

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-VI appears to be that they all relate to a "modified arrestin". The specification defines the term "modified arrestin" as "an arrestin that has one or more ubiquitin moieties and a label molecule associated or attached to the arrestin" (pg 20). Thus claim 1 encompasses modified arrestin that encompasses an arrestin and a ubiquitin molecule with the following functional characteristic: "increased affinity for a GPCR, as compared to the affinity of a wild-type increased affinity for a GPCR, and wherein increased affinity means that the arrestin remains associated with the GPCR and traffics with the GPCR into endosomes, and wherein the arrestin does not dissociate at or near the plasma membrane". However, the specification further indicates that the addition of ubiquitin to an arrestin results in this functional characteristic: "the addition of ubiquitin moieties to arrestin increases the affinity of arrestin to binding to a GPCR" (pg 26). Therefore, the special technical feature appears to be any ubiquitinated arrestin that associates with a GPCR. Shenoy et al (2001. Science. 294: 1307-1313; cited as reference C24 on the 6/19/06 IDS) teach a modified arrestin that meets the limitations of claim 1. Shenoy et al teach ubiquitinated β-arrestin that associates with the β_2-adrenergic receptor (which is a GPCR), wherein said ubiquitination is required for receptor internalization. Therefore, the technical feature linking the inventions of group I-VI does not constitute a special technical feature as defined by PCT rule 13.2, as it does not define a contribution over the prior art.

Elections of species

In addition to the above restriction requirement, two or three elections of species are required as follows.

(I) This application contains claims directed to more than one species of label of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species are as follows: (1) radioisotope, (2) epitope tag, (3) affinity label, (4) enzyme, (5) fluorescent group or (6) chemiluminescent group.

(II) This application contains claims directed to more than one species of arrestin of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species are as follows: (1) a visual arrestin, (2) a cone arrestin, (3) β-arrestin 1 and (4) β-arrestin 2. Furthermore, if β-arrestin 2 is elected with respect to the first species election, the following election of a subspecies of engineered variant of β-arrestin 2 is also required. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The subspecies are as follows: (1) EYFP-Barr2-Ub; (2) EYFP-Barr2-Ub48; and (3) EGFP-Barr2-Ub48. Applicants are further required to identify the amino acid and nucleic acid sequences in the Sequence Listing and claims that correspond to the elected subspecies.

(III) This application contains claims directed to more than one species and subspecies of GPCR of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species are as follows: (1) Class A and (2) Class B. The subspecies of Class A are (1) μ opioid, (2) β1AR, (3) β2AR, (4) dopamine D1A receptor and (5) endothelin1A receptor (pg 2 of the specification). The subspecies of Class B are (1) V2R, (2) angiotensin AT1a, (3) neurotensin1, (4) thyrotropinreleasing hormone receptor and (5) neurokinin NK-1 receptor.

Applicant is required, in reply to this action, to elect: (I) a single species of label, (II) a single species of arrestin, and if β-arrestin 2 is elected, a single subspecies of engineered variant and (III) a single species of GPCR and a single subspecies within said species, to which the claims shall be restricted if no generic claim is finally held to

be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each label, arrestin, or GPCR is a structurally different molecule. Lack of unity is shown because these treatments lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

zch

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646